VIRGINIA:

IN THE CIRCUIT COURT FOR THE CITY OF ROANOKE

CHANCE EVERETT BAKER

Plaintiff,

v.

ALAUNUS PHARMACEUTICAL, LLC
Serve: Office of the Secretary of the Commonwealth
1111 East Broad Street, 4th Floor
Richmond, VA 23219

and

IMAGE GUIDED PAIN MANAGEMENT, P.C., d/b/a INSIGHT IMAGING ROANOKE,
Serve: Herman Marshall, III,
Registered Agent
10 S. Jefferson Street
Suite 1400
Roanoke, VA 24011

Case No._____

and

INSIGHT HEALTH SERVICES CORP.
Serve: Office of the Secretary of the Commonwealth
1111 East Broad Street, 4th Floor
Richmond, VA 23219

and

INSIGHT HEALTH CORP.
Serve: CT Corporation
Registered Agent
4701 Cox Rd Suite 301
Glen Allen, VA 23060

and

INSIGHT HEALTH SERVICES HOLDINGS CORP.
Serve: Office of the Secretary of the Commonwealth
1111 East Broad Street, 4th Floor
Richmond, VA 23219

Frith & Ellerman LAW FIRM, PC

EXHIBIT
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A

and)
)
ROBERT F. O'BRIEN, MD)
Serve: 2923 Franklin Road)
Roanoke, VA 24014)
)
Defendants.)

COMPLAINT

Chance Everett Baker ("plaintiff") files his complaint against Alaunus Pharmaceutical, LLC, Image Guided Pain Management, P.C., d/b/a Insight Imaging Roanoke, Insight Health Services Corp., Insight Health Corp., Insight Services Holdings Corp., and Robert T. O'Brien, MD ("defendants") and in support thereof states as follows:

Parties

1. Chance Everett Baker (plaintiff) is a resident of Vinton, Virginia.

2. New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center (NECC) is a Massachusetts corporation that maintains its principal place of business at 697 Waverly Street in Framingham, Massachusetts.

3. NECC is a compounding pharmacy, in the business of making, selling and distributing prescription medications across the United States, including Virginia.

4. Alaunus Pharmaceuticals LLC, (Alaunus) is a Massachusetts limited liability company, involved in selling and distributing compounded pharmaceutical products made by NECC and its affiliate companies.

5. Image Guided Pain Management, P.C., d/b/a Insight Imaging Roanoke is a Virginia Corporation with its principal place of business at 2923 Franklin Road SW, Roanoke, Virginia.

6. Image Guided Pain Management, P.C. is in the business of distributing and administering pain management products and devices to its patients.

7. Insight Health Services Corp. is a Delaware corporation with its principal place of business in California.

8. Insight Health Services Holdings Corp. is a Delaware corporation with its principal place of business in California.

9. Insight Health Corp. is Delaware Corporation with a registered agent in the Commonwealth of Virginia.

10. In 2010, the predecessor company of Image Guided Pain Management, P.C. (Center for Advanced Imaging) was purchased by Insight Health Services Holdings Corp., and has since that time, been part of the Insight Imaging family of companies.

11. Image Guided Pain Management, PC operates with and through the following companies to provide services to patients, bill patients, and obtain/administer medications on behalf of patients: Insight Health Corp., Insight Health Services Holdings Corp., and Insight Health Services Corp.

12. Together, these four corporate entities employ the physicians and staff at Image Guided Pain Management, PC, namely Robert O'Brien, MD and John M. Mathis, MD.

13. Dr. O'Brien is an agent, employee, and officer of Image Guided Pain Management, P.C.

14. Dr. O'Brien is licensed in the Commonwealth of Virginia to provide diagnostic radiology services.

15. Image Guided Pain Management, PC, Insight Health Services Corp, Insight Health Corp, Insight Health Services Holdings Corp., and Dr. O'Brien are hereinafter referred to collectively as "Insight defendants."

16. All of the named defendants conducted business, provided services and engaged in business in the City of Roanoke, Virginia.

Factual Background

17. Throughout 2012, NECC manufactured batches of an injectable steroid medication known as methylprednisolone acetate (hereinafter "MPA").

18. NECC and Alaunus marketed, distributed, and sold products including MPA to various healthcare providers in the Commonwealth of Virginia, including but not limited to Image Guided Pain Management, PC, in the City of Roanoke.

19. Specifically, the Insight defendants purchased on behalf of Image Guided Pain Management, PC and its patients, the following from NECC:

a. 200 doses of methylprednisolone acetate PF 80mg/ml injectable, I ML shipped to Insight on 5/29/12.

b. 200 doses of methylprednisolone acetate PF 80mg/ml injectable, I ML shipped to Insight on 6/15/12.

c. 200 doses of methylprednisolone acetate PF 80mg/ml injectable, I ML shipped to Insight on 7/9/12.

d. 200 doses of methylprednisolone acetate PF 80mg/ml injectable, I ML shipped to Insight on 7/26/12.

e. 200 doses of methylprednisolone acetate PF 80mg/ml injectable, I ML shipped to Insight on 8/17/12.

f. 200 doses of methylprednisolone acetate PF 80mg/ml injectable, I ML shipped to Insight on 9/6/12.

20. These products were distributed by Alaunus on behalf of NECC, to Insight Guided Pain Management, PC and its affiliated companies.

21. In September 2012, Massachusetts health officials in conjunction with the United States Food and Drug Administration (FDA) began an investigation of NECC's compounding methods, facility and products, specifically investigating sterilization techniques, autoclaving and other safety procedures related to drug manufacturing.

22. On September 26, 2012, NECC recalled three lots of MPA which had been produced in their facility and distributed by Alaunus across the United States: Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013.

23. On October 3, 2012, the Massachusetts Department of Health in conjunction with the Centers for Disease Control and Prevention (CDC), closed NECC upon discovering contaminated compounds within the facility.

24. On October 6, 2012, NECC recalled all products in circulation that were compounded and distributed from their Massachusetts facility.

25. Between September 26, 2012 and October 3, 2012, an agent of NECC and or the FDA notified an agent of Image Guided Pain Management, PC and their affiliated companies, that Insight defendants received product made from the recalled lots of MPA listed above.

26. Upon information and belief, Image Guided Pain Management, PC learned NECC products manufactured on or after May 2012 could likely be tainted and contain fungal contamination.

27. Since the October 6, 2012 recall, the CDC and the FDA have tested and identified bacterial and/or fungal contamination in the recalled products from NECC.

28. These bacterial and fungal contaminants are known to cause disease in humans such as meningitis.

29. NECC filed a petition of bankruptcy in December 2012 with the U.S. Bankruptcy Court for the District of Massachusetts.

30. In August 2012, the plaintiff was referred by his orthopedic physician to Image Guided Pain Management, PC for care and treatment of his back pain.

31. Plaintiff received an MRI of the lumbar spine from the Insight defendants on August 3, 2012.

32. On September 12, 2012, plaintiff returned to Image Guided Pain Management, PC and was administered an epidural steroid injection (hereinafter ESI) by Dr. O'Brien, under direct x-ray visualization.

33. The injection included 80mg of MPA which was injected into the plaintiff's spinal column.

34. The purpose of the injection was to relieve plaintiff's chronic and severe back pain.

35. At all times relevant hereto, plaintiff received MPA created by, marketed by, sold by, and distributed by NECC and Alaunus, at Insight Imaging's office on Franklin Road in Roanoke, Virginia.

36. Insight defendants state on their website they provide image guided therapies, including minimally invasive image guided injections of steroids into patients.

37. Insight defendants represented to the plaintiff, as reflected on the plaintiff's bill and medical records, that the steroid used and injected into the plaintiff's spinal column on September 12, 2012, was a product called Depo-Medrol.

38. Depo-Medrol is the trade name for a medication manufactured by a subsidiary of Pfizer, Inc. to treat skin irritations, allergies, and inflammation.

39. Despite the representation by Insight defendants to the plaintiff that he received an injection of Depo-Medrol (80mg), plaintiff was injected with 80 mg of MPA (methylprednisolone acetate) manufactured by NECC, and sold by defendant Alaunus to Image Guided Pain Management, PC and its subsidiary companies.

40. The medication sold by NECC and Alaunus to the Insight defendants and administered to the plaintiff on September 12, 2012, was part of the contaminated medication identified by the CDC.

41. On or about October 4, 2012, the plaintiff received a phone call from a representative of Insight Defendants advising that the injection he received may have been contaminated.

42. On or about October 6, 2012, the plaintiff began to experience symptoms consistent with fungal meningitis including severe headache.

43. When his symptoms continued to increase, the plaintiff went to Carilion Roanoke Memorial Hospital emergency room on October 7, 2012.

44. Plaintiff was diagnosed with, and received treatment for, fungal meningitis.

45. The Virginia Department of Health made a determination that plaintiff's meningitis was related to the contaminated injection he received from the defendants on September 12, 2012.

46. The plaintiff required approximately six weeks of acute hospital care, therapy and treatment as a result of his fungal meningitis infection.

Count I – Alaunus Pharmaceuticals LLC. – Negligence Per Se

47. Alaunus Pharmaceutical LLC (Alaunus) is in the business of wholesaling and distributing medications made by NECC and its affiliated companies.

48. Virginia Code section 54.1-3401, defines "Wholesale distribution" as distribution of prescription drugs to persons other than consumers or patients, subject to the exceptions set forth in § 54.1-3401.1; "Wholesale distributor" as any person engaged in wholesale distribution of prescription drugs including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses conducting wholesale distributions, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies conducting wholesale distributions.

49. The injectable steroid MPA is one of the pharmaceutical products that Alaunus distributed to the Insight defendants.

50. Virginia Administrative Code section 18 VAC 110-50-30 requires persons and entities that distribute medications to obtain a license and permit from the Virginia Board of Pharmacy.

51. Alaunus was obligated to comply with Virginia Administrative Code section 18 VAC 110-50-30 et seq. by obtaining a license.

52. Virginia Code § 54.1-3408.01 requires all prescriptions shall contain the first and last name of the patient for whom the drug is prescribed.

53. Virginia Code § 54.1-3435 states it shall be unlawful for any person to engage in the wholesale distribution of prescription drugs in this Commonwealth without a valid unrevoked license issued by the Board.

54. Upon information and belief, Alaunus does not now and has never held a license issued by the Virginia Board of Pharmacy to sell, manufacture, distribute or wholesale pharmaceutical products.

55. Alaunus failed to comply with the above relevant Virginia Code and Virginia Administrative Code sections by:

a. Failing to obtain a license and permit in the Commonwealth;

b. Failing to make their distribution and warehouse facilities open for inspection;

c. Failing to maintain medications in a safe and sterile environment;

d. Issuing and distributing prescriptions in mass quantifies that did not contain names of patients for whom the medication was being prescribed;

e. Failing to quarantine drugs that had been adulterated; and

f. Distributing drugs that were not fit for human consumption.

56. Alaunus' actions outlined above were in direct violation of Virginia law.

57. The plaintiff was in the class of persons intended to be protected by these applicable state laws, and the plaintiff suffered the type of harm the statute was enacted to prevent.

58. The aforesaid acts of and/or omissions by the defendant constitutes negligence per se.

59. Alaunus' conduct was willful and wanton in that the defendant acted in conscious disregard of the rights and safety of Virginia patients including the plaintiff, and with reckless indifference as to the consequences.

60. As a result of Alaunus' negligence and violation of Virginia law, the plaintiff suffered damages which are described hereafter.

Count II – Insight Defendants - Negligence Per Se

61. Plaintiff hereby incorporates all allegations contained prior to this paragraph.

62. Virginia Code § 54.1-3408.01 requires that all prescriptions shall contain the first and last name of the patient for whom the drug is prescribed.

63. Insight defendants issued prescriptions to Alaunus and NECC without including patient names, ordering medications such as steroid injections in bulk, 200 units at a time.

64. This practice may have saved the Insight defendants money by buying in bulk, but such practice is in direct violation of Virginia law.

65. The plaintiff was in the class of persons intended to be protected by these applicable state laws, and the plaintiff suffered the type of harm the statute was enacted to prevent.

66. The aforesaid acts of and/or omissions by the Insight defendants constitute negligence per se.

67. The Insight defendants acted in conscious disregard of the rights and safety of Virginia patients including the plaintiff, and with reckless indifference as to the consequences.

68. As a result of Insight defendants' negligence and violation of Virginia law, the plaintiff suffered damages which are described hereafter.

Count III – Insight Defendants - Negligence

69. Plaintiff hereby incorporates all allegations contained prior to this paragraph.

70. According to the U. S. Food and Drug Administration (FDA), NECC had been cited previously for failure to use proper sterilization practices which lead to the death of a Tennessee resident in 2004.

71. Despite NECC's history of improper practices, the Insight defendants negligently purchased steroids from NECC when it knew, or should have known, that its products were not reasonably safe to administer to patients.

72. The Insight defendants knowingly purchased these medications that were compounded in bulk. Bulk compounding is a direct violation of Virginia law.

73. The Insight defendants negligently and carelessly selected a compounding pharmacy to provide their medicines when they knew, or should have known, that NECC did not follow proper practices, procedures and state law for the safe manufacture of MPA.

74. As a direct and proximate result of the Insight defendants' negligence, lack of care, and other wrongful acts, plaintiff has suffered damages which are described hereafter.

Count IV - Insight Defendants - Fraud

75. Plaintiff hereby incorporates all allegations contained prior to this paragraph.

76. The Insight defendants represented to the plaintiff and his health insurer in plaintiff's medical records and statement of charges that the medication provided to plaintiff in September 2012 through the epidural steroid injection was 80mg of Depo-Medrol.

77. The plaintiff had previously received Depo-Medrol from his treating orthopedic physician and from the Insight defendants in 2012.

78. When the recall of NECC products occurred in early October 2012, patients from Insight were notified they had been injected with MPA made by NECC, and not Depo-Medrol, a Pfizer product.

79. When the Insight defendants represented to the plaintiff, his referring healthcare providers, and his insurance company, that he had received a Depo-Medrol injection, the statement was patently false.

80. The difference between Depo-Medrol and the MPA used by Insight defendants is significant.

81. The Insight defendants knew the representation was false as the medications used were not labeled Depo-Medrol; rather, they contained a label stating methylprednisolone acetate made by New England Compounding Pharmacy.

82. The Insight defendants had the intent to mislead when they informed the patient, his physicians and insurance company that the plaintiff had been given Depo-Medrol.

83. The plaintiff has suffered significant damages as a result of the defendants' misrepresentations and use of a product other than Depo-Medrol.

Count V – Alaunus- Express Warranty

84. Plaintiff hereby incorporates all allegations contained prior to this paragraph.

85. Defendant Alaunus marketed and distributed into the stream of commerce the methylprednisolone acetate (MPA).

86. Upon information and belief, defendant Alaunus expressly warranted that the MPA was safe and effective.

87. The MPA placed into the stream of commerce by NECC and Alaunus did not conform to these express representations because it was contaminated with fungus.

88. As a direct and proximate result of defendant's breach of the express warranties, plaintiff has suffered damages which are described hereafter.

Count VI – Insight Defendants – Express Warranty

89. Upon information and belief, the Insight defendants made express representations the steroid administered to plaintiff was safe, effective, manufactured by Pfizer and was, in fact, Depo-Medrol.

90. The Insight defendants breached their express warranties under Virginia Code Section 8.2-313.

91. As a direct and proximate result of the Insight defendants' breach of express warranties regarding the safety and effectiveness of the steroid, plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and will continue to suffer such damages in the future.

Count VII – All Defendants – Implied Warranty

92. Plaintiff incorporates by reference each and every allegation set forth in the preceding paragraphs and further alleges as follows.

93. Defendants designed, manufactured, tested, marketed, distributed into the stream of commerce, and administered the methylprednisolone acetate (MPA).

94. At the time defendants designed, manufactured, tested, marketed, distributed into the stream of commerce, and administered the MPA, defendants knew the use for which the MPA was intended and impliedly warranted the MPA to be of merchantable quality and safe for such use.

95. Plaintiff reasonably relied upon the skill and judgment of the defendants as to whether the MPA was of merchantable quality and safe for its intended use.

96. Defendants breached their implied warranty of merchantability under Virginia Code Section 8.2-314.

97. Contrary to the defendants' implied warranties, the MPA was not of merchantable quality or safe for its intended use, because the MPA was unreasonably dangerous as described above.

98. As a direct and proximate result of the defendants' breach of implied warranties regarding the safety and effectiveness of the MPA, the plaintiff has suffered significant damages hereafter defined.

Damages

As a result of the defendants' negligence, breach of express and implied warranties, and statutory or regulatory violations, plaintiff was seriously and permanently injured. He has suffered physical pain, discomfort and mental anguish, and these will continue in the future; he has incurred substantial expenses for treatment by physicians and related medical care, and in the future he will or may likely continue to incur medical expenses as a direct result of being injected with contaminated doses of MPA.

WHEREFORE, for the reasons stated above, plaintiff respectfully requests that he be awarded a judgment against the defendants, jointly and severally, in the amount of FIVE MILLION DOLLARS ($5,000,000.00) in compensatory damages and THREE HUNDRED AND FIFTY THOUSAND DOLLARS ($350,000) in punitive damages, together with interest and costs of this proceeding, including attorneys' fees, as well as such other and further relief as may be appropriate under the circumstances of this case.

Trial by jury is requested.

CHANCE EVERETT BAKER

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